SPECIAL ARTICLE

Utilization of do-it-yourself artificial pancreas systems in the management of patients with type 1 diabetes: a position statement of the Pump School Education Initiative by Diabetes Poland

Andrzej Gawrecki[1]*, Tomasz Klupa[2,3]*, Aleksandra Araszkiewicz[1], Bartłomiej Matejko[2,3], Agnieszka Szadkowska[4], Bogumił Wolnik[5], Elektra Szymańska-Garbacz[6], Przemysława Jarosz-Chobot[7], Małgorzata Myśliwiec[8], Leszek Czupryniak[9], Maciej T. Małecki[2,3], Dorota Zozulińska-Ziółkiewicz[1]

1 Department of Internal Medicine and Diabetology, Poznan University of Medical Sciences, Poznań, Poland
2 Department of Metabolic Diseases, Jagiellonian University Medical College, Kraków, Poland
3 Department of Metabolic Diseases, University Hospital, Kraków, Poland
4 Department of Pediatrics, Diabetology, Endocrinology and Nephrology, Medical University of Lodz, Łódź, Poland
5 Department of Hypertension and Diabetology, Medical University of Gdańsk, Gdańsk, Poland
6 Department of Internal Medicine and Nephrodiabetology, Medical University of Lodz, Łódź, Poland
7 Department of Children's Diabetology, School of Medicine in Katowice, Medical University of Silesia, Katowice, Poland
8 Department of Pediatrics, Diabetology and Endocrinology, Medical University of Gdańsk, Gdańsk, Poland
9 Department of Internal Diseases and Diabetology, Warsaw Medical University, Warsaw, Poland

Correspondence to:
Tomasz Klupa, MD, PhD, Department of Metabolic Diseases, Jagiellonian University Medical College, ul. Kopernika 15, 31-501, Kraków, Poland, phone: +48 12 424 83 00, email: tomasz.klupa@uj.edu.pl
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* AG and TK contributed equally to this work.

Insulin pump therapy is reimbursed in Poland for all individuals with type 1 diabetes (T1D) under the age of 26 and is becoming an increasingly popular method of insulin delivery for this population of patients. The Pump School Education Initiative by Diabetes Poland (Szkoła Pompowa Polskiego Towarzystwa Diabetologicznego) organizes advanced training for doctors who treat patients with continuous subcutaneous insulin infusion. People with T1D have to regularly monitor their glucose levels, using either a glucose meter or a continuous glucose sensor, and adjust their insulin dose as required. Recent data have demonstrated that only a minority of adults and youth with T1D in the United States meet American Diabetes Association goals for glycated hemoglobin A_{1c} levels.[1] Diabetes technology, including systems of semiautomatic (hybrid) or automatic insulin delivery, called an artificial pancreas (AP), has made considerable progress over recent decades. AP systems (APSs) may be considered as a promising therapeutic option for people with diabetes, as they enable insulin pumps to automatically administer insulin with only a limited intervention by patients. The APSs work through a combination of insulin pump, with continuous glucose monitoring and algorithm-directed insulin pump delivery. The insulin pump is in constant communication with continuous glucose monitoring to obtain current blood glucose estimates, and insulin release is adjusted accordingly to maintain blood glucose within the target range. Details of all recent insulin dosing (both basal and bolus) are maintained by the insulin pump. Clinical trials published to date have demonstrated both improved glycemic outcomes and improved health-related quality of life outcomes while simultaneously reducing the burden of self-management.[2-4]

Ready-to-use APSs currently offered by industry are either still in development or very expensive. As a result, a do-it-yourself movement of APS (DIY APS) has emerged. The DIY community can support progress in this area and accelerate the development of commercial automated insulin delivery (closed-loop) systems. The currently available DIY loop software options include Loop, Open APS, Android APS, and others, which are hybrid closed-loop systems.[5-7] These systems use an

algorithm to control basal insulin requirements. Patients must continue to use the bolus calculator by entering the amount of carbohydrates to deliver bolus insulin.[8] The development of open protocols is supported by the Juvenile Diabetes Research Foundation, the leading global organization funding type 1 diabetes research. The results of DIY APS implementation, shared mostly through social media, show good glycemic control[9] with reduced blood glucose variability, reduction (or elimination) of hypoglycemic episodes, reduction in psychosocial burden, and significant improvement of the quality of life.[10] As a result, many DIY APS users are very enthusiastic about these systems; however, it is important to note that there have been no clinical trials designed to demonstrate their safety and effectiveness; accordingly, they have no regulatory body approval. The systems, therefore, must be used wisely, as patients are relying on unsupported hardware and software.

For doctors, medico-legal implications may arise from endorsing the use of nonapproved technology.[10] Barnard et al[11] recently emphasized that the current population of DIY APS users consists of highly engaged and highly tech-savvy individuals; it is not clear if the wider population of T1D patients would be willing or able to engage in the demands of building and maintaining their own DIY APS. Additionally, many legislative questions around diabetes technology, in general, remain unaddressed[12]; therefore, under current regulations, patients using DIY APS do so at their own risk.

Despite all these concerns, we have to be prepared for a rapid development of DIY APS, along with a correspondingly rapidly growing number of DIY APS users, especially in countries with lower incomes. DIY APSs are used around the world by patients at all ages. As health care providers, we should monitor new development in this field and be as helpful as possible to the patients who decide to use a DIY APS. Specifically, we should:

1 Perform studies evaluating target blood glucose levels, the number of hypoglycemic episodes, and hemoglobin A_{1c} levels, as well as the quality of life related to the use of DIY APSs.[13] Such studies must be performed in a safe environment (eg, camps, hospitals), with safety issues considered as primary outcomes.

2 Document case reports which demonstrate patient successes and experiences, but also record adverse events.

3 Encourage therapeutic teams to become familiar with the DIY APSs and learn different algorithms or mechanisms of glucose-dependent insulin adjustment.

4 Actively participate in media (including social media) debates concerning the effectiveness and safety of DIY APSs.[14]

5 Push for new legislation to make DIY APS "legal" as long as they meet safety criteria.

6 Engage in the preselection process for the DIY APS, with consideration of patients' knowledge, technical abilities, and compliance.

The DIY APS has created new possibilities for the management of patients with diabetes not under direct physician control; however, one must not overlook the role of diabetologists, who are responsible for the appropriateness and safety of insulin therapy. While it is the task of the patient to build the DIY APS, the algorithm runs and does the decision-making process based on previous settings of the insulin pump (basal rate, insulin sensitivity factor, insulin to carbohydrate ratio, duration of insulin action, blood glucose target), which have been determined by the diabetologist. The doctor must not only monitor therapeutic outcomes achieved by the device but also ensure its safety.

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